

January Session, 2015

## Proposed Substitute Bill No. 957

LCO No. 5040

## AN ACT CONCERNING REVISIONS TO THE REGENERATIVE MEDICINE RESEARCH FUND AND THE CONNECTICUT BIOSCIENCE INNOVATION FUND, AND THE CONSOLIDATION OF CERTAIN FUNDS OF CONNECTICUT INNOVATIONS, INCORPORATED.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- 1 Section 1. Subsection (a) of section 32-41jj of the general statutes is
- 2 repealed and the following is substituted in lieu thereof (Effective July
- 3 1, 2015):
- 4 (a) As used in sections 32-41jj to 32-41mm, inclusive, <u>as amended by</u>
- 5 <u>this act</u>, and section 4-28e:
- 6 (1) "Embryonic stem cell research oversight committee" means a
- 7 committee established in accordance with the National Academies'
- 8 Guidelines for Human Embryonic Stem Cell Research, as amended
- 9 from time to time.
- 10 (2) "Cloning of a human being" means inducing or permitting a
- 11 replicate of a living human being's complete set of genetic material to
- 12 develop after gastrulation commences.
- 13 (3) "Gastrulation" means the process immediately following the
- 14 blastula state when the hollow ball of cells representing the early

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- 16 that results in the formation of the three primary germ layers, the
- 17 ectoderm, mesoderm and endoderm.
- 18 (4) "Embryonic stem cells" means cells created through the joining of
- 19 a human egg and sperm or through nuclear transfer that are
- 20 sufficiently undifferentiated such that they cannot be identified as
- 21 components of any specialized cell type.
- 22 (5) "Nuclear transfer" means the replacement of the nucleus of a
- 23 human egg with a nucleus from another human cell.
- 24 (6) "Eligible institution" means (A) a nonprofit, tax-exempt academic
- 25 institution of higher education, (B) a hospital that conducts biomedical
- 26 research, or (C) any entity that conducts biomedical research or
- 27 regenerative medicine research.
- 28 (7) "Regenerative medicine" means the process of creating living,
- 29 functional tissue to repair or replace tissue or organ function lost due
- 30 to aging, disease, damage or congenital defect. Regenerative medicine
- 31 includes basic stem cell research.
- 32 (8) "Financial assistance" means any and all forms of grants,
- 33 extensions of credit, loans or loan guarantees, equity investments or
- 34 other forms of financing.
- 35 Sec. 2. Section 32-41kk of the general statutes is repealed and the
- 36 following is substituted in lieu thereof (*Effective July 1, 2015*):
- 37 (a) There is established the "Regenerative Medicine Research Fund",
- 38 which shall be a separate, nonlapsing account within the General
- 39 Fund. The fund may contain any moneys required or permitted by law
- 40 to be deposited in the fund and any funds received from any public or
- 41 private contributions, gifts, grants, donations, bequests or devises to
- 42 the fund. The chief executive officer of Connecticut Innovations,
- 43 Incorporated, (1) shall [make grants-in-aid] <u>award financial assistance</u>
- 44 from the fund in accordance with the provisions of subsection (b) of
- 45 this section, and (2) may enter into agreements with other entities,

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including, but not limited to, the government of any state or foreign country for the purpose of advancing research collaboration opportunities for recipients of [grants-in-aid] <u>financial assistance</u> under this section.

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(b) The Regenerative Medicine Research Advisory Committee established pursuant to section 32-41ll, as amended by this act, shall develop an application for [grants-in-aid] financial assistance under this section for the purpose of conducting regenerative medicine research and may receive applications from eligible institutions for such [grants-in-aid] financial assistance. The Regenerative Medicine Research Advisory Committee shall require any applicant for [a grantin-aid] financial assistance under this section to conduct regenerative medicine research to submit (1) a complete description of the applicant's organization, (2) the applicant's plans for regenerative medicine research and proposed funding for such research from sources other than the state, and (3) proposed arrangements concerning financial benefits to the state as a result of any patent, royalty payment or similar rights developing from any proposed research made possible by the awarding of such [grant-in-aid] financial assistance. The Regenerative Medicine Research Advisory Committee shall direct the chief executive officer of Connecticut Innovations, Incorporated, with respect to the awarding of such [grants-in-aid] <u>financial assistance</u> after considering recommendations from [the Regenerative Medicine Research Peer Review Committee established pursuant to section 32-41mm] the peer review panel selected by said advisory committee pursuant to section 32-41mm, as amended by this act.

(c) Commencing with the fiscal year ending June 30, 2006, and for each of the thirteen consecutive fiscal years thereafter, until the fiscal year ending June 30, 2019, not less than ten million dollars shall be available from the Regenerative Medicine Research Fund for [grants-in-aid] <u>financial assistance</u> to eligible institutions for the purpose of conducting regenerative medicine research. Any balance of such amount not used for such [grants-in-aid] financial assistance during a

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- fiscal year shall be carried forward for the fiscal year next succeeding for such [grants-in-aid] <u>financial assistance</u>.
- Sec. 3. Section 32-41*ll* of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2015*):
- 84 (a) (1) There is established a Regenerative Medicine Research 85 Advisory Committee. The committee shall consist Commissioner of Public Health, or the commissioner's designee, the 86 87 chief executive officer of Connecticut Innovations, Incorporated, or the 88 chief executive officer's designee, and eight members who shall be 89 appointed as follows: Two by the Governor, one of whom shall have 90 background and experience in stem cell or regenerative medicine 91 research and one of whom shall have background and experience in 92 business or financial investments; one each by the president pro 93 tempore of the Senate and the speaker of the House of Representatives, 94 who shall have background and experience in private sector 95 regenerative medicine research and development; one each by the 96 majority leaders of the Senate and House of Representatives, who shall 97 be academic researchers specializing in regenerative medicine 98 research; one by the minority leader of the Senate, who shall have 99 background and experience in either private or public sector 100 regenerative medicine research and development or related research fields, including, but not limited to, embryology, genetics or cellular 101 102 biology; and one by the minority leader of the House of 103 Representatives, who shall have background and experience in the 104 field of bioethics. Members shall serve for a term of four years 105 commencing on October first, except that members first appointed by 106 the Governor and the majority leaders of the Senate and House of 107 Representatives shall serve for a term of two years. No member may 108 serve for more than two consecutive four-year terms. All initial 109 appointments to the committee shall be made by October 1, 2005. Any 110 vacancy shall be filled by the appointing authority.
- 111 (2) The Regenerative Medicine Research Advisory Committee shall 112 include eight additional members who shall be appointed as follows:

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Two by the Governor, who shall have backgrounds and experience in 113 114 business or financial investments; one each by the president pro 115 tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector 116 117 regenerative medicine research and development; one each by the 118 majority leaders of the Senate and House of Representatives, who shall 119 be academic researchers specializing in regenerative medicine 120 research; one by the minority leader of the Senate, who shall have 121 background and experience in either private or public sector 122 regenerative medicine research and development or related research 123 fields, including, but not limited to, embryology, genetics or cellular 124 biology; and one by the minority leader of the House of 125 Representatives, who shall have background and experience in 126 business, law or ethics. Members shall serve for a term of four years, 127 except that (A) members first appointed by the Governor and the 128 majority leaders of the Senate and House of Representatives pursuant 129 to this subdivision shall serve for a term of two years and three 130 months, and (B) members first appointed by the remaining appointing 131 authorities shall serve for a term of four years and three months. No 132 member appointed pursuant to this subdivision may serve for more 133 than two consecutive four-year terms. All initial appointments to the 134 committee pursuant to this subdivision shall be made by July 1, 2006. 135 Any vacancy shall be filled by the appointing authority.

(b) The chief executive officer of Connecticut Innovations, Incorporated, or the chief executive officer's designee, shall serve as chairperson of the Regenerative Medicine Research Advisory Committee.

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- (c) All members appointed to said advisory committee shall work to advance regenerative medicine research. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from said advisory committee.
- (d) Notwithstanding the provisions of any other law, it shall not

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constitute a conflict of interest for a trustee, director, partner, officer, stockholder, proprietor, counsel or employee of any eligible institution, or for any other individual with a financial interest in any eligible institution, to serve as a member of said advisory committee. All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10. Members may participate in the affairs of said advisory committee with respect to the review or consideration of [grant-in-aid] applications for financial assistance, including the approval or disapproval of such applications, except that no member shall participate in the affairs of said advisory committee with respect to the review or consideration of any [grant-inaid application for financial assistance filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity.

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(e) The Regenerative Medicine Research Advisory Committee shall develop, in consultation with Connecticut Innovations, Incorporated, a donated funds program to encourage the development of funds other than state appropriations for regenerative medicine research in the state, (2) examine and identify specific ways to improve and promote for-profit and not-for-profit regenerative medicine research and research in related areas in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing regenerative medicine-related businesses, recruiting new regenerative medicine-related businesses to the state and recruiting scientists and researchers in such field to the state, (3) administer a regenerative medicine research [grant] assistance program that shall provide [grants-in-aid] financial assistance to eligible institutions for the advancement of regenerative medicine research in the state pursuant to section 32-41kk, as amended by this act, (4) monitor the regenerative medicine research conducted by eligible institutions that receive such [grants-in-aid] financial assistance, and (5) prepare a comprehensive strategic plan for the Regenerative Medicine Research Fund, established pursuant to section 32-41kk, as amended by this act, and [grants-in-aid made] financial

LCO No. 5040 **6** of 12 181 <u>assistance awarded</u> from said fund that shall include, but need not be

- 182 limited to, identification of specific methods or strategies to (A)
- 183 achieve the scientific and economic development objective of said
- 184 fund, (B) build innovation capacity, and (C) sustain investments of
- 185 moneys received by said fund.
- 186 Connecticut Innovations, Incorporated, shall serve 187 administrator of the Regenerative Medicine Research Fund and shall, 188 in consultation with the Regenerative Medicine Research Advisory 189 Committee: (1) Develop the application for the [grants-in-aid] <u>financial</u> 190 assistance authorized under subsection (b) of section 32-41kk, as 191 amended by this act; (2) review such applications; (3) review 192 recommendations of the Regenerative Medicine Research Advisory 193 Committee, established pursuant to section 32-41mm, as amended by 194 this act; (4) prepare and execute any assistance agreements or other 195 agreements in connection with the awarding of such [grants-in-aid] 196 financial assistance; (5) develop performance metrics and systems to 197 collect data from recipients of such [grants-in-aid] <u>financial assistance</u>; 198 (6) collect information from such recipients concerning each recipient's 199 employment statistics, business accomplishments and performance 200 outcomes, peer review articles and papers published, partnerships and 201 collaborations with other entities, licenses, patents and invention 202 disclosures, scientific progress as it relates to the commercialization of 203 intellectual property funded by such [grants-in-aid] <u>financial</u> 204 assistance, efforts to commercialize such intellectual property, and 205 other funds received for research; and (7) performing such other 206 administrative duties as the Regenerative Medicine Research Advisory 207 Committee deems necessary.
- Sec. 4. Section 32-41mm of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2015*):
- [(a) (1) There is established a Regenerative Medicine Research Peer Review Committee. Said peer review committee shall consist of five members.
- 213 (2) On and before September 30, 2014, all members appointed by the

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Commissioner of Public Health to the committee shall (A) have demonstrated knowledge and understanding of the ethical and medical implications of regenerative medicine research or related research fields, including, but not limited to, embryology, genetics or cellular biology, (B) have practical research experience in regenerative medicine research or related research fields, including, but not limited to, embryology, genetics or cellular biology, and (C) work to advance regenerative medicine research. Members shall serve for a term of four years commencing on October first, except that three members first appointed by the Commissioner of Public Health shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the Regenerative Medicine Research Advisory Committee established pursuant to section 32-41ll. All initial appointments to said peer review committee shall be made by October 1, 2005. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from said peer review committee.

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(3) On and after October 1, 2014, each member appointed by the Commissioner of Public Health pursuant to subdivision (2) of this subsection may serve to the conclusion of his or her current term at which time members shall be appointed by the chief executive officer of Connecticut Innovations, Incorporated, as follows: Members appointed to said peer review committee shall: (A) Have demonstrated knowledge and understanding of the ethical and medical implications of regenerative medicine research or research in a related field, including, but not limited to, embryology, genetics or cellular biology; (B) have practical research experience in regenerative medicine research or research in a related field, including, but not limited to, embryology, genetics or cellular biology; and (C) work to advance regenerative medicine research. Members shall serve for a term of four years, except that three members first appointed by the chief executive officer of Connecticut Innovations, Incorporated, shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the

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- 249 Regenerative Medicine Research Advisory Committee established
- 250 pursuant to section 32-41ll. Any member who fails to attend three
- 251 consecutive meetings or who fails to attend fifty per cent of all
- 252 meetings held during any calendar year shall be deemed to have
- 253 resigned from said peer review committee.
- (b) All members shall be deemed public officials and shall adhere to
- 255 the code of ethics for public officials set forth in chapter 10. No
- 256 member shall participate in the affairs of the committee with respect to
- 257 the review or consideration of any grant-in-aid application filed by
- such member or by any eligible institution in which such member has
- 259 a financial interest, or with which such member engages in any
- 260 business, employment, transaction or professional activity.]
- 261 (a) The Regenerative Medicine Research Advisory Committee
- 262 established pursuant to section 32-41ll, as amended by this act, shall
- select an independent panel of professional peer reviewers who shall:
- 264 (1) Have demonstrated knowledge and understanding of the ethical
- 265 and medical implications of regenerative medicine research or related
- 266 research fields, including, but not limited to, embryology, genetics or
- 267 <u>cellular biology, (2) have practical research experience in regenerative</u>
- 268 medicine research or related research fields, including, but not limited
- 269 to, embryology, genetics or cellular biology, and (3) work to advance
- 270 <u>regenerative medicine research.</u>
- [(c)] (b) Prior to the awarding of any [grants-in-aid] financial
- 272 <u>assistance</u> for regenerative medicine research pursuant to section 32-
- 273 41kk, as amended by this act, [the Regenerative Medicine Research
- 274 Peer Review Committee] said peer reviewers shall review all
- 275 applications submitted by eligible institutions for such [grants-in-aid]
- 276 <u>financial assistance</u> and make recommendations to the Regenerative
- 277 Medicine Research Advisory Committee established pursuant to
- section 32-41ll, as amended by this act, with respect to the ethical and
- 279 scientific merit of each application.
- [(d)] (c) [Members of the Regenerative Medicine Research Peer
- 281 Review Committee] Said peer reviewers may receive compensation

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- 282 from Connecticut Innovations, Incorporated, for reviewing grant-in-
- 283 aid applications submitted by eligible institutions. The rate of
- 284 compensation shall be established by the board of directors of
- 285 Connecticut Innovations, Incorporated.
- [(e)] (d) The Regenerative Medicine Research [Peer Review
- 287 Committee] Advisory Committee, in consultation with said peer
- 288 reviewers, shall establish guidelines for the rating and scoring of such
- 289 applications.
- [(f) All members of said peer review committee] (e) All said peer
- 291 reviewers shall become and remain fully cognizant of the National
- 292 Academies' Guidelines for Human Embryonic Stem Cell Research, as
- 293 amended from time to time, and shall utilize said guidelines to
- 294 evaluate each grant-in-aid application.
- Sec. 5. Section 32-41aa of the general statutes is repealed and the
- 296 following is substituted in lieu thereof (*Effective from passage*):
- 297 For the purpose of this section and sections 32-41bb to 32-41dd,
- 298 inclusive:
- 299 (1) "Administrator" means Connecticut Innovations, Incorporated,
- 300 in its capacity as administrator of the Connecticut Bioscience
- 301 Innovation Fund established pursuant to section 32-41cc.
- 302 (2) "Advisory committee" means the Bioscience Innovation
- 303 Advisory Committee established pursuant to section 32-41bb.
- 304 (3) "Early-stage business" means a business that has been in
- operation for not more than [three] seven years and is developing or
- 306 testing a product or service that is (A) not yet available for commercial
- 307 release, or (B) commercially available in a limited manner, including,
- 308 but not limited to, market testing of prototypes and clinical trials that
- 309 <u>have not begun phase II evaluation.</u>
- 310 (4) "Eligible recipient" means a duly accredited college or university,
- a nonprofit corporation or a for-profit start-up or early-stage business.

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- 312 (5) "Financial assistance" means any and all forms of grants, 313 extensions of credit, loans or loan guarantees, equity investments or 314 other forms of financing.
- 315 (6) "Return on investment" means any and all forms of principal or 316 interest payments, guarantee fees, returns on equity investments, 317 royalties, options, warrants and debentures and all other forms of 318 remuneration to the administrator in return for any financial assistance 319 offered or provided.
- 320 (7) "Phase II Evaluation" means a phase II clinical trial conducted 321 under the auspices of an independent peer-reviewed protocol that has 322 been reviewed and approved by one of the National Institutes of 323 Health or the federal Food and Drug Administration.

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Sec. 6. (NEW) (Effective July 1, 2015) (a) Effective July 1, 2015, (1) the Business Environmental Clean-Up Revolving Loan Fund established under section 32-23z of the general statutes and in effect on June 30, 2015, and (2) the Environmental Assistance Revolving Loan Fund established under section 32-23qq of the general statutes and in effect on June 30, 2015, shall be combined with and become part of the Connecticut Growth Fund established under section 32-23v of the general statutes and in effect on June 30, 2015, provided all subfunds established under section 32-23qq of the general statutes shall become subfunds within the Connecticut Growth Fund. As of July 1, 2015, cash, notes, receivables and all other assets, liabilities, appropriations, authorizations, allocations and attributes then pertaining to the Business Environmental Clean-Up Revolving Loan Fund and the Environmental Assistance Revolving Loan Fund shall be transferred to the Connecticut Growth Fund. All loans, guarantees and lines of credit outstanding under sections 32-23z and 32-23qq of the general statutes on June 30, 2015, shall be treated as having been made, committed or extended from the Connecticut Growth Fund established under section 32-23v of the general statutes, and all payments received by the corporation on account thereof shall be credited or deposited to the Connecticut Growth Fund.

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(b) On and after July 1, 2015, in addition to, and not in limitation of, the powers of the corporation in making loans from the Connecticut Growth Fund to eligible borrowers under section 32-23v of the general statutes, the corporation may make loans from the Connecticut Growth Fund, in the manner therein provided, to any person for any purpose as would have been permitted by section 32-23z or 32-23qq of the general statutes if made from the Business Environmental Clean-Up Revolving Loan Fund or the Environmental Assistance Revolving Loan Fund, respectively.

(c) All applications for loans under sections 32-23z and 32-23qq of the general statutes pending on June 30, 2015, and authorized on or after July 1, 2015, shall be funded from the Connecticut Growth Fund established under section 32-23v of the general statutes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	July 1, 2015	32-41jj(a)
Sec. 2	July 1, 2015	32-41kk
Sec. 3	July 1, 2015	32-41 <i>ll</i>
Sec. 4	July 1, 2015	32-41mm
Sec. 5	from passage	32-41aa
Sec. 6	July 1, 2015	New section

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